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## **SAFETY DEVICE WITH TRIGGER MECHANISM**

### **Field of the Invention**

The invention relates to a safety device, and in particular a trigger mechanism thereof, for hypodermic needles.

### **Background to the Invention**

This invention takes as its starting point PCT application number PCT/GB00/04416 (SCIENTIFIC GENERICS LIMITED) filed 20 November 2000 and entitled 'Safety Device'. The closest prior art known to the applicant is this PCT application and any art acknowledged or on record for its patent prosecution since filing.

Figures 5a – 5g in PCT application number PCT/GB00/04416 and their associated text explain that formed on top of each arm, 541, 542 towards the back inside edge of each, is a first (540b) and a second (540a) half of a priming button 540, which, when pushed forwards by a user, causes the back halves 541a, 542a of the locking arms to pivot outwardly about the hinge regions 541d, 542d.

This PCT-published priming button arrangement 540 etc has been superseded by the present invention which not only works much better but on quite

different principles. These differences, and their inherently inventive nature when compared with this most relevant prior art document, will become apparent as this present specification unfolds.

Other trigger mechanisms exist in this field and can be broadly summarised as:

- Those using single sided spring actions to return to the safe position, these have a tendency for the end caps to tilt towards the needle axis in use and have the potential to snag the needle tip preventing use;
- Those using coiled/compressed spring actions to return to the safe position; here the number of parts in the assembly precludes the use of modern single-piece moulding techniques, incurring undesirable additional manufacturing costs.

An objective of the present invention is to provide an improved safety device incorporating a trigger mechanism that includes a priming function which guards against accidental so-called "needle stick" when not in use and enables the needle to be unsheathed during use in a controlled manner and then automatically resheathed to ensure safe further contact.

#### Summary of the Invention

In its broadest aspect the invention provides a safety device with trigger mechanism which is intended to form part of, and to operate in conjunction with, a needle-sheathing safety device of the general kind exemplified by the Figures 5a – 5g embodiments of PCT/GB00/04416 but whose scope is defined by the claims of this present specification.

Those claims, as numbered and set out at the end of this disclosure, form an inherent part of the disclosure in their own right.

### Brief Description of the Drawings

The accompanying drawings show, by way of example only, one safety device trigger mechanism embodying the invention.

In the drawings (in which Figures 1a to 1g correspond to figures 5a to 5g of PCT/GB00/04416):-

Figure 1a is a perspective view of the closest prior art safety device in which pivoted locking arms extend along the length of the device;

Figure 1b is a schematic cross-sectional view of the prior art safety device of Figure 1a along the line b-b in the safe position of Figure 1a;

Figure 1c is a schematic cross-sectional view of the prior art safety device of Figure 1a along the line b-b in a primed position;

Figure 1d is a schematic cross-sectional view of the prior art safety device of Figure 1a along the line b-b in an injection position;

Figure 1e is a schematic cross-sectional view similar to Figures 1b to 1c showing the prior art safety device and a needle and needle-luer combination, illustrating how the combination is mounted into the prior art safety device;

Figures 1f and 1g are schematic plan views of the prior art safety device of Figures 1a to 1e illustrating how an elastic band is mounted onto the prior art safety device.

Figure 2 is a perspective view of the safety device and trigger mechanism according to the invention in which the trigger mechanism is in the unprimed position;

Figure 3 is a perspective view showing that same trigger mechanism in the primed position;

Figure 3 is a perspective view showing that same trigger mechanism in the primed position;

Figures 4a, 4b and 4c are schematic cross-sectional views illustrating the effect of the trigger mechanism on the geometry of the safety device in respectively the unprimed, primed and the automatic release from primed positions;

Figure 5a is an enlarged perspective view of the trigger mechanism;

Figure 5b is a preferred profile of the trigger mechanism;

Figure 5c is an alternative profile of the trigger mechanism; and

Figure 5d is a schematic cross-sectional view of the trigger mechanism.

Figures 1a to 1g should first be studied in conjunction with the relevant text of application PCT/GB00/04416. The present description proceeds from there.

#### Detailed Description of the Embodiment

With reference to Figures 2 to 5 a safety device assembly 10 is presented comprising a needle receiving portion 11, a sheath portion 12 and a trigger mechanism 13.

The needle-receiving portion 11 operably receives and holds a needle (see figures 4a, 4b, 4c) and/or a needle luer combination and assembly of such.

The sheath portion 12 comprises a nose plate 14 having a bore 15 therethrough, with resiliently flexible legs 16, 17 extending between the needle receiving portion 11 and the nose plate 14 and operably connected at these junctures by hinges 18, 19 on both legs 16, 17.

The safety device assembly 10 is formed by a one piece injection moulding process.

Each resiliently flexible leg 16, 17 of the safety device 10 has a central knee joint 20, 21 separating the back portion of the legs 16a, 17a and the front portion of the legs 16b, 17b. The configuration of the leg portions 16a, 17a; and knee joints 20, 21 ensure that longitudinal forces acting on the nose plate 14 reinforce the natural bias. Resilient means in the form of an elastic band 22 disposed over the rear portion of the legs 16a, 17a prevents deforming and outward flexing of the legs 16, 17 increasing resistance to accidental needle stick when the assembly is unprimed and ensuring automatic return of arms 16, 17 and the nose plate 14 to the extended position when the assembly is no longer in the primed position. The band 22 is held in place by securing lugs 23a, 23b disposed on opposing legs 16a, 17a on the outside face of the legs 16a, 17a. Intermediate the securing lugs 23a, 23b about the upper face of the legs 16a, 17a is located release means 24 comprising rigid tabs 24a, 24b. The tabs 24a, 24b form a triangular cut-out region which acts as a lead-in for the trigger mechanism 13.

The trigger mechanism 13 comprises an elongate actuating lever 13 fixably attached at one end to the needle receiving portion 11 and having a second end disposed over the back region of the legs 16, 17 when forced between tabs 24a, 24b it separates the legs 16, 17 in a direction away from each other, overcoming the inherent bias of the legs 16, 17 and the restraining force of band 22.

The tab-engaging portion 25 of the lever 13 is shaped and sized to engage the release means 24 and separate the rigid tabs 24a, 24b when pressed in a downward direction and in turn separate the legs 16, 17 whilst not obstructing the passage of the needle.

The profile of the elongate actuator lever 13 comprises a large radius 26 at the rear and a smaller radius 27 at the front. A strengthening rib 28 on the

underside of the actuating lever 13 is disposed between the engaging portion 25 and the entirety of the small radius 27.

In operation, a user would grasp the safety device assembly 10 by placing a thumb on the upper face of the trigger lever 13 above the strengthening rib 28 whilst at the same time having a finger, on the underside of the assembly, supporting the assembly when the user then presses the trigger, the pressure of such a movement forces the engaging portion of the actuating lever 13 between the release means 24 and separates the tabs 24a, 24b, the engaging portion 25 is progressively securely latched between and under each leg 16a, 17a in a position immediately below the tabs 24a, 24b.

In this, the so-called primed position, subsequently applied longitudinal forces acting on the nose plate 14 will cause the legs 16, 17 to flex outwardly and unsheath the needle for use. Performing the injection (i.e. continuing such longitudinal application of force along the needle axis) causes the legs 16, 17 to flex apart to a maximum position and the actuating lever 13 engaging portion 25 is then released from its secured latched position and rises up, under its own resilience, out of the way of the legs.

When the longitudinal force acting on the nose plate 14 is removed, the needle retracts; the natural resilience of the legs 16, 17 plus the action of band 22 causes the legs 16, 17 to automatically close around the needle until they are once more in the closed position of Figure 2. They are then geometrically so biased that further longitudinal forces acting on the nose plate 14 will be resisted rather than cause the needle to be exposed.

The double-curved profile of the trigger mechanism 13 gives it in-built equilibrium retaining the relative positions between the engaging portion above the release means 24. Its shape also intuitively leads the user to correctly use the assembly 10 to perform an injection. In other words, he will tend naturally to downwardly press it rather than attempt to push it forwards.

The trigger has a number of other advantageous features.

The downward engaging movement of portion 25 as it separates the legs 16, 17 is such that further downward pressure as the engaging portion 25 is latched into a primed position tends to retain inline the centres of the legs 20, 21 and the centre of the needle;

The end profile of the engaging portion 25 is so shaped to separate the arms 16, 17 evenly whilst retaining the geometry of the legs 16, 17 – if the centres of the legs 20, 21 are not kept far enough apart one leg would have a tendency to lock and hinder movement but the present configuration ensure both legs 16, 17 move apart equally;

The end profile has a squared off front end, so that when the engaging portion 25 is latched in the primed position there is sufficient clearance for the needle to move without impacting the trigger mechanism 13. In an alternative embodiment (Figure 5c) it is so shaped and sized to embrace the needle without restricting movement of the needle; this is also advantageous in its own right.

The curvy profile of the actuating lever 13 comprises two radii, a large rearward radius 26 to prevent the likelihood of plastic creep giving the assembly 10 a longer life, inherent-reusability and to assist the spring back action of the lever 13 and a smaller forward radius 27 giving the so-called working end of the lever 13 with the engaging portion 25 a low profile.

The strengthening rib 28 limits the deformation of the curved shape trigger 13, in use. It permits deformation in the first curve 26 which in turn assists spring-back but strengthens the second curve 27 restricting the movement of the engaging portion 25 downwards rather than forwards.